



INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary) PTO Form 1449	Atty Docket No. 117789-042	Application No. 10/825,257
	Applicant Burns et al.	Date Submitted March 7, 2008
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U.S. PATENT DOCUMENTS							
Examiner's Initials		Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate
		3332950	07-25-67	Blumberg et al.			
		3493657	02-03-1970	Lewenstein et al.			
		3879555	04-22-1975	Pachter et al.			
		4361553	11-30-1982	Loh et al.			
		4457933	07-03-1984	Gordon et al.			
		4582835	04-15-1986	Lewis et al.			
		4760069	07-26-1988	Rzeszotarski et al.			
		4769372	09-06-1988	Kreek			
		4863928	09-05-1989	Atkinson et al.			
		4882335	11-21-1989	Sinclair			
		4889860	12-26-1989	Rzeszotarski et al.			
		4910158	03-20-1990	Meyers et al.			
		4935428	06-19-1990	Lewis et al.			
		5075341	12-24-1991	Mendelson et al.			
		5086058	02-04-1992	Sinclair			
		5096715	03-17-1992	Sinclair			
		5317022	05-31-1994	Borsodi et al.			
		5321012	06-14-1994	Mayer et al.			
		5352680	10-04-1994	Portoghese et al.			
		5834477	11-10-1998	Mioduszewski			
		RE36,547	2000-02-01	Crain et al.			
		2003/0232744	12-18-2003	Crain et al.			

FOREIGN PATENT DOCUMENTS							
Examiner's Initials		Document Number	Publication Date	Country	Class	Subclass	Translation Yes No
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							Yes	No
		9406426	03-31-1994	PCT				
		9503804	09-02-95	PCT				
		85/50585	06-05-1986	AU				
		88/18970	01-18-1990	AU				
		88/26432	06-08-1989	AU				
		87/01703	03-26-1987	WO				
		92/24023	02-18-1993	AU				
		94/06426	03-31-1994	WO				
		95/03804	02-09-1995	WO				
		144,243	06-12-1985	EP				
		415,693	03-06-1991	EP				
		319,243	06-07-1989	EP				
		352,361	01-31-1990	EP				

Examiner's Initials	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Crain et al., "Method of Simultaneously Enhancing analgesic Potency and Attenuating Dependence Liability Caused By Exogenous and Endogenous Opioid Agonists," Ex Parte Reexamination Certificate No. US RE 36,547 F1 issued March 22, 2005.
	Crain et al., "Method of Simultaneously Enhancing analgesic Potency and Attenuating Dependence Liability Caused By Morphine and Other Bimodally-Acting Opioid Agonists," Ex Parte Reexamination Certificate No. 5,767,125 C1 issued June 14, 2004.
	Crain et al., "Method of Simultaneously Enhancing analgesic Potency and Attenuating Dependence Liability Caused By Morphine and Other Bimodally-Acting Opioid Agonists," Ex Parte Reexamination Certificate No. 5,580,876 C1 issues June 15, 2004.
	Crain et al., "Method of Simultaneously Enhancing analgesic Potency and Attenuating Dependence Liability Caused By Morphine and Other Bimodally-Acting Opioid Agonists," Ex Parte Reexamination Certificate No. 6,096,756 C1 issued February 3, 2004.
	Cepeda MS et al., entitled "Addition of ultralow dose naloxone to postoperative morphine PCA: unchanged analgesia and opioid requirement but decreased incidence of opioid side effects," Pain 107: 41-46, 2004.
	Gan, TJ et al., entitled "Opioid-sparing Effects of a Low-dose infusion of Naloxone in Patient-administered Morphine Sulfate," Anesthesiology 87:1075-81, 1997
	Joshi, GP et al., "Effects of Prophylactic Nalmefene on the Incidence of Morphine-related Side Effects in Patients Receiving Intravenous Patient-controlled Analgesia," Anesthesiology 90: 1007-11, 1999.
	Kayser V et al., entitled "Cross-tolerance between analgesic low doses of morphine and naloxone in arthritic rats," Brain Research, 405: 123-129, 1987.

Examiner: /Renee Claytor/	Date Considered: 09/02/2008
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	Goodman & Gilman's THE PHARMACEUTICAL BASIS OF THERAPEUTICS, 9 th Edition, pages 523-526, 1996
	Request for Ex Parte Reexamination of U.S. Patent No. RE 36,547.
	Request for Ex Parte Reexamination of U.S. Patent No. 5,767,125.
	Request for Ex Parte Reexamination of U.S. Patent No. 5,580,876.
	Request for Ex Parte Reexamination of U.S. Patent No. 6,362,194.
	Request for Ex Parte Reexamination of U.S. Patent No. 6,096,756.
	Dum and Herz, 1981, "In vivo Receptor Binding of the Opiate Partial Agonist, Buprenorphine, Correlated with its Agonistic and Antagonistic Actions," Br. J. Pharmac. 74:627-633.
	Budd, 1987, "Clinical use of opioid antagonists," Balliere's Clinical Anesthesiology 1(4):993-1011.
	Goodman & Gilman, 1975, The Pharmaceutical Basis of Therapeutics, 5 th Edition, Macmillan, New York, Chapter 15, p. 273.
	Crain & Shen, 1995, Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic co-treatment. Proc. Natl. Acad. Sci. U.S.A. 1995 Nov. 7;92(23): 10540-10544.
	Konieczko et al. 1988, "Antagonism of morphine-induced respiratory depression with nalmefene," Br. J. Anaesth. 61:318-323.
	Barsan et al. 1989, "Duration of Antagonistic Effects of Nalmefene and Naloxone in Opiate-induced Sedation for Emergency Department Procedures," J. Emerg. Med. 7(2); 155-161.
	Abu-Elheiga et al. 2001, "Continuous fatty acid oxidation and reduced fat storage in mice lacking Acetyl-coA carboxylase 2," Science 291:2613-16.
	Goodman & Gilman (eds.), 1975, The Pharmacological Basis of Therapeutics, 5 th Edition, Macmillan, New York, Chapter 15, "Narcotic Analgesics and Antagonists" (by J.H. Jaffe and W.R. Martin) pages 245-283.
	Budd K., 1985 "The use of the opiate antagonist, naloxone, in the treatment of intractable pain," Neuropeptides. 5(4-6):419-22.
	Attal et al. 1989, "Behavioral evidence for the bidirectional effect of systemic naloxone in a model of experimental neuropathy in the rat," Brain Res. 494(2):276-84.
	Kayser et al. 1981, "Dose-dependent analgesic and hyperalgesic effects of systemic naloxone in arthritic rats," Brain Res. 226(1-2):334-8.
	Kayser et al. 1984, "Further evidence for a bidirectional effect of naloxone on the pain threshold in tolerant and non-tolerant arthritic rats," Neuropeptides. 5(1-3):49-52.
	Malaise & Franchimont, 1987, "Methods of clinical and biological assessment of rheumatoid arthritis," Scand. J. Rheumatol. Suppl. 65:81-4, Review.
	Specification of US Patent No. RE 36,547
	Shen and Crain, <u>Regulatory Peptides</u> , in press (1993).
	Shen and Crain, <u>Brain Research</u> , 597:74-83 (1992).

Examiner: /Henee Claytor/	Date Considered: 09/02/2008
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	Shen and Crain, <u>Brain Research</u> , 575:13-24 (1992).
	Wang et al., <u>Chinese J. Pharm. Toxicol.</u> 6:36-40 (1992) and English translation thereof.
	Bo-Yi, Quin, <u>New Drugs and Clinical Remedies</u> , 12:119-123 (1992) and English translation thereof.
	Lange, et al., <u>Toxicol. Applied Pharm.</u> , 54:177-186 (1980).
	Terwillinger et al., <u>Brain Research</u> , 548:100-110 (1991).
	Shen et al., <u>Brain Research</u> , 559:130-138 (1991).
	Crain and Shen, <u>Trends Pharmacol. Sci.</u> 11:77-81 (1990).
	Fujimoto et al., <u>Neuropharmacol.</u> 29:609-617 (1990).
	Shen and Crain, <u>Brain Research</u> , 531:1-7 (1990).
	Shen and Crain, <u>Brain Research</u> , 491:227-242 (1989).
	North, <u>Trends Neurosci.</u> , 9:114-117 (1986).
	Magnan, et al., <u>Nauyn-Schmiedelberg's Arch. Pharmacol.</u> , 319:197-205 (1982).
	Bentley and Hardy, <u>J. American Chem. Soc.</u> , 89:3281-3286 (1967).
	Bentley and Hardy, <u>Proc. Chem. Soc.</u> , p. 220 (1963).
	Holmes and Fujimoto, <u>Anesth. Analg.</u> , 77:116-1173 (1993).
	Miaskowski and Levine, <u>Brain Research</u> , 596:41-45 (1992).
	Vaccarino et al., <u>Pain</u> , 36:103-109 (1989).
	Cappell et al., <u>Pharmacology Biochemistry & Behavior</u> , 34:425-427 (1989).
	Gardner, <u>Substance Abuse</u> , 2d ed., pp. 70-99 (1992).
	Shen and Crain, <u>Brain Res.</u> , 636:286-297 (1994).
	Greenstein et al., <u>Subst. Abuse</u> , 2d ed., pp. 562-573 (1992).
	Gonzales, et al., <u>Drugs</u> , 35:193-213 (1988).
	Shen and Crain, <u>J. Neurosci.</u> , 14:5570-5579 (1994).
	Blane, et al. <u>Brit. J. Pharmacol. Chemother.</u> , 30:11-22 (1967).
	Fujimoto et al., <u>J. Pharm. Exp. Ther.</u> , 251:1045-1052 (1989).
	Gilman et al., <u>Intern. J Neurosci.</u> , 48:321-324 (1989).
	Gilman et al., <u>J. Neurol. Sciences</u> , 49:41-49 (1981).
	Gillman et al., <u>South African J. Science</u> , 83:560-563 (1987).
	Pederson et al., <u>Brit. J. Anaesth.</u> 57:1045-1046 (1985).

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	Schmidt, et al., <u>Anesthesia</u> , 40:583-586 (1985).
	Bergman et al., <u>Arch. Int. Pharmacodyn.</u> , 291:229-237 (1988).
	Levine, et al., <u>J. Clin Invest.</u> , 82:1574-1577 (1988).
	Crain and Shen, <u>J. Pharmacol. Exp. Ther.</u> , 260:182-186 (1992).
	Goldberg, et al., <u>Science</u> , 166:1548-1549 (1969).
	Lasagna, <u>Proc. Royal Soc. Med.</u> , 58(11):978-983 (1965).
	Taiwo, et al., <u>J. Pharm. Exp. Therapeutics</u> , 249:97-100 (1989).
	Arts, et al., <u>Pharm. Biochemistry Behavior</u> , 46:623-629 (1993).
	Horan et al., <u>J. Pharm. Exp. Therapeutics</u> , 265:1446-1454 (1993).
	Kayser et al., <u>Brain Research</u> , 371:37-41 (1986).
	Takemori, et al., <u>J. Pharm. Exp. Therapeutics</u> , 266:121-124 (1993).
	Crain et al., <u>Brain Research</u> , 455:99-109 (1988).
	Buchsbaum et al., <u>Nature</u> , 270:620-622 (1977).
	Levine, <u>Nature</u> , 278:740-741 (1979).
	Gillman et al. <u>European J. Pharmacol.</u> , 61:175-177(1980).
	Levine, <u>Brain Research</u> , 365:377-378 (1986).
	Budd, K., <u>Ballieres Clin. Anesthesiology</u> , 1:993-1011 (1987).
	Gillman and Lichtigfield, <u>South African Med. J.</u> , 70:650-651 (1986).
	Berkow, Robert et al., <u>The Merck Manual of Diagnosis and Therapy</u> , 16 th Edition, Merck & Co., Inc., NY 1992 pp. 1558-1559.
	Reynolds, JEF Martindale, <u>The Extra Pharmacopoeica</u> , 30 th Ed., The Pharmaceutical Press, London, 1993, pp. 687-688
	Datta, et al., <u>Peptides</u> , Vol. 3, pp. 433-437, 1992.
	Tremblay, et al., <u>Psychopharmacology</u> , Vol. 49, pp. 41-48, 1976.
	Shen and Crain, <u>Brain Research</u> , Vol. 636, pp. 286-291, 1994.

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